In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 16-852V
(to be published)

AMY CARTER, *as parent and next friend of* A.C., *a minor*,	*	Special Master Oler
Petitioner,	*	Filed: October 16, 2018
v.	*	Attorneys' Fees and Costs; Reasonable Basis.
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Howard Scott Gold, Gold Law Firm, LLC, Wellesley Hills, MA, for Petitioner.
Voris Edward Johnson, U.S. Department of Justice, Washington, D.C., for Respondent.

DECISION ON FINAL ATTORNEYS' FEES AND COSTS[1]

On July 20, 2016, Amy Carter ("Petitioner") filed a petition on behalf of her minor child, A.C., seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program"),[2] alleging that A.C. "suffered from a reaction which was diagnosed as Mental Developmental Delay, Mixed receptive-expressive language disorder[,] and Gross Motor Delay" as a result of her Diphtheria, Tetanus, and Pertussis ("DTaP") and Haemophilus Influenza Type b

[1] This Decision will be posted on the Court of Federal Claims' website. **This means the ruling will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). If, upon review, I agree that the identified materials fit within this definition, I will redact such material from public access. Otherwise, the Decision in its present form will be available. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

("Hib") vaccinations administered on July 22, 2013.[3] Petition ("Pet."), ECF No. 1. On June 26, 2018, Petitioner filed a Motion for a Decision Dismissing Petition (ECF No. 49); a decision dismissing the petition for insufficient proof was issued on June 29, 2018. ECF No. 50. Judgment was entered on July 30, 2018. ECF No. 53.

On May 24, 2018, Petitioner filed a Motion for Attorneys' Fees and Costs.[4] Fees Application, ECF No. 44. Petitioner requests attorneys' fees in the amount of $11,622.00, and costs in the amount of $935.75, totaling $12,557.75. *Id*. Petitioner's counsel asserts that Petitioner incurred no costs in this case. *Id*. Respondent opposes the motion, and contends that Petitioner failed to establish a reasonable basis for her claim. Resp. to Fees App. For the reasons set forth herein, Petitioner's Motion for Attorneys' Fees and Costs is denied.

I. Factual History

A.C. was born on May 19, 2013. Ex. 1; Ex. 8 at 4. The following day, she received a Hepatitis B vaccination. Ex. 8 at 1. She had a weight check visit on May 21, 2013 and June 12, 2013. Ex. 4 at 6, 10. On June 20, 2013, A.C. had a four-week well child exam and it was noted that she "spits up a lot, arches back, [is] fussy, [and has] several large vomits." *Id.* at 13. The record also notes A.C.'s development. Regarding her gross motor development, she "lifts head slight from prone position." *Id.* at 13. Regarding her language development, she "responds to sound." *Id.* Regarding her personal or social development, she "regards face." *Id*.

On July 22, 2013, A.C. had a two-month well child visit and received the following vaccinations: DTaP, Hib, Pneumococcal, Polio, and Rotavirus. *Id.* at 15. The record notes her development. Regarding her fine motor development, she "follows past midline, grasps." *Id.* at 16. Regarding her gross motor development, she "lifts head 45 degrees from prone position, head steady in upright position, [and she] is bringing hand to mouth." *Id.* Regarding her language development, she coos and laughs. *Id.* Regarding her personal or social development, she "regards face, smiles responsively, [and is] alert." *Id.*

On August 15, 2013, A.C. presented to the pediatrician with a history of cold symptoms, cough, and congestion for the past four days. *Id.* at 18. She did not have a fever and her appetite was normal. *Id.* Upper respiratory symptoms were reported by her parent and the record notes that she had a sick contact from daycare. *Id.* at 19. A.C. was reported to be fussy and had diminished activity, specifically, she was not sleeping well. *Id*. Her rapid RSV test was negative. *Id*. Her x-ray exam was unremarkable. *Id*. at 51.

[3] This case was initially assigned to now-retired Special Master Hastings (ECF No. 5), reassigned to Special Master Corcoran on October 4, 2017 (ECF No. 32), and then reassigned to my docket on December 1, 2017 (ECF No. 35).

[4] For clarification, I will refer to Petitioner's motion as "Fees App." and cite to the page numbers of Petitioner's motion in accordance with the CM/ECF generated header.

A.C. had a four-month well child visit on September 30, 2013. Ex. 6 at 1. She received the following vaccinations: pneumococcal conjugate, rotavirus-pentavalent, Hib, and DTaP-Hep B-IPV. *Id*. at 3-4. Her physical exam revealed that she was irritable and was crying excessively. *Id*. at 3. She was also smiling, playful, active, and alert. *Id*. Her level of distress was noted to be uncomfortable. *Id*. The record also notes her development. Regarding her fine motor development, she "reaches and grab[s] object" and "brings hands together." *Id*. Regarding her gross motor, she "pulls to sit [with] no lag, rolls from front onto back, sits with head steady in upright position, lifts head and chest off surface, uses arms to push chest off surface." *Id*. Regarding her language development, she "turns to voice, laughs and squeal[s], vocalizes [and] coos." *Id*. Regarding her personal or social development, she "smiles responsively" and "seeks eye contact." *Id*. The record did not note any developmental delay. *Id.*

On December 2, 2013, A.C. had a six-month well child visit. Ex. 4 at 21. She received a rotavirus-pentavalent vaccination and a DTaP-Hep B-IPV vaccination. *Id.* at 23. Regarding her fine motor development, she "transfers object" and "works for toy." *Id.* Regarding her gross motor development, she "pulls to sit [with] no head lag, sits without support, [and] stands holding on." *Id.* Regarding her language development, she "babbles." *Id.* Regarding her personal or social development, she "plays peek-a-boo" and "turns toward voices." *Id.* A.C. was noted to be napping and sleeping on her own in at least eight-hour stretches. *Id.* The record did not note any developmental delay. *Id.*

On May 19, 2014, A.C. (now one-year old) experienced "fatigue/lethargy, feeding or appetite problems, [and] vomiting." *Id.* at 29. The record notes that she was waking up during the night, and, for the past week, she was "more fussy than normal." *Id.* The record also notes that four days prior to her visit, she vomited three times and "has not had an appetite since then." *Id.* The history of present illness ("HPI") notes that A.C. is a "12 month female with one week of fussy behavior [and] 2 weeks of URI [symptoms]." *Id.* at 30. Physical examination revealed A.C. to be "irritable and excessive crying and active and alert." *Id*. Her level of distress was noted as uncomfortable. *Id.* The doctor assessed A.C. with painful teething (teething syndrome) and a URI. *Id*. at 31.

A.C. had her 12-month well child visit on June 2, 2014. The record from this visit notes that she was experiencing cold symptoms, including congestion, runny nose, and waking up throughout the night. *Id*. at 25. She was also noted to be fussy for the past five to six days. *Id*. She was warm to touch and had a decreased appetite during this visit. *Id*. Her gross motor symptoms revealed that she "does not pull to stand, does not stand well alone, [and] does not walk holding onto furniture." *Id*. at 27. Her fine motor symptoms indicated "pincer grasp, scribbles spontaneously, [and] drinks from cup." *Id*. The medical record notes that A.C.'s mother wanted to postpone shots until the following week because of A.C.'s URI. *Id*. at 28.

A.C.'s mother scheduled an in-home developmental evaluation, which was conducted by the Harford County Infants and Toddlers Program on June 10, 2014. Ex. 7. A.C.'s mother provided the evaluators with background information regarding A.C.'s health. While A.C. was noted to currently be in good health, sleeping throughout the night, and taking naps two times per day, A.C.'s mother reported that A.C. had difficulty latching and had a clipped tongue when she

was two days of age. *Id*. at 1. She further reported "concerns related to screaming fits that [A.C.] had since 2 months of age, difficulty transitioning to table foods and motor skills." *Id*. at 1. During the evaluation, A.C. was able to transition in and out of a sitting position on her own, but was unable to crawl forward. *Id*. at 2. A.C. did not use the furniture to pull into a standing position. *Id*. Near the end of the evaluation, A.C. became frustrated and started to cry. *Id*. Her sibling was able to calm her after providing her with a bottle and rocking her to sleep. *Id*. Regarding A.C.'s screaming fits, her mother described her fits lasting for three or four hours, ending only when A.C. had exhausted herself. *Id*. She also stated that the fits began the day after A.C.'s two-month vaccinations. *Id*. Her mother recorded a video of A.C.'s screaming fits, and the evaluators noted that "during the fit [A.C.] screamed intensely, without crying, she remained tight and stiff." *Id*. The evaluation results show that A.C.'s fine motor development was appropriate for her age, and that she had a 25% (or greater) delay "in the areas of gross motor, language, social/emotional development, cognition and concerns with the area of daily living skills."[5] *Id*. at 4.

A.C. had an 18-month well child visit on February 26, 2015 (although she was 21 months old at this visit). *Id*. at 35. The medical record notes that A.C. did not have her 15-month or 18-month physical exams and that she did not have her 12-month shots. *Id*. A.C. was sleeping throughout the night and napping once per day. *Id*. at 37. Regarding her fine motor development, she was noted to turn book pages, stack three to four blocks, and scribble spontaneously. *Id*. Regarding her gross motor development, the records state that she "runs, walks backwards, climbs on furniture, kicks ball forward, throws ball, walks up steps, walks well, [and] climbs." *Id*. Regarding her language development, she is able to point to body parts, she knows 10 to 15 words, she is able to combine two different words, she understands and follows basic commands, and she is able to name an animal or object in a picture. *Id*. However, it is noted that she is "not talking much, says 4-5 words." *Id*. The medical record also notes that she had "infants and toddlers for physical therapy" and that she does sign language. *Id.* Regarding her personal/social development, she is able to feed herself, imitate housework, and remove her clothes. *Id*. Her parent declined the Hepatitis A vaccine as she "has had bad reaction with DTP in past." *Id*. at 38. "MODIFIED CHECKLIST FOR AUTISM IN TODDLERS" is listed under the Assessment/Plan section of the records. *Id.*, emphasis in original.

On June 15, 2016, A.C. had a well-child visit. *Id*. at 1. The HPI notes that there is a "[h]igh concern for developmental delay today" and that she has "had services for gross motor which she was discharged from but no other services at this time." *Id*. at 3. The HPI further notes that A.C.'s prolonged crying began after her two-month vaccinations. *Id*. Her first few years she was "more fussy but that is not the case now." *Id*. A.C. is noted to not be able to answer questions; however, she is able to repeat "very well and has good articulation." *Id*. A.C. "has a tick, in which when in a standing position, she runs her arms down her body" and this occurs "more when she is excited."

[5] "Based on [A.C.'s] adjusted age of 13 months; scores of 9.75 months or less would be considered a 25% or greater delay." Ex.7 at 2 (emphasis omitted). Her fine motor development (age range of 10 months) was normal; her language development (age range of 9 months) was noted as an area of delay; her daily living development (age range of l0 months) was noted as an area of concern; her social/emotional development (age range of 8 months) was noted as an area of delay. *Id*. Her cognition (age range of 9 months) was noted as an area of delay. *Id*.

Id. The doctor assessed A.C. as a well three-year-old child with developmental delay; specifically, she has "significant delay in comprehension; however does have good speech and articulation when repeating." *Id*. at 4. The plan notes that A.C. needs a full developmental screening at Kennedy Krieger Institute ("the Institute") and that she will "likely need significant services with special educators." *Id*.

A.C.'s initial evaluation at the Institute occurred on July 5, 2016. Ex. 5 at 1. The record notes that she has a history of language delay. *Id*. It also notes that despite not receiving immunizations according to the regular schedule, she was current on her immunizations. *Id*. The record reflects a parental history that after receiving "a number of DTP immunizations" A.C. had episodes of extreme crying. *Id*. Review of symptoms notes that A.C. "now has good gross motor skills for age..." and that "there are no specific fine motor concerns."[6] *Id*. Regarding her language delay, the record notes that "most of her verbalizations consists of echolalia." *Id*. She is unable to understand questions and has difficulty understanding commands. *Id*. A.C., since infancy, "has had a bilateral shaking arm movement that is repetitive and appears to draw both of her hands towards midline"; her parents report that such arm movement began around the age of six months. *Id*. A.C. "has a tremendous fear/aversion to being placed on her back (as in when she is having her diaper changed)." *Id*. She is scheduled for a formal audiology evaluation in the afternoon and has yet to have a formal ophthalmology evaluation. *Id*. A.C. had a neurologic examination and developmental assessment. *Id*. at 3. She was noted to have "an 'upside down' pattern of language delay, with expressive language skills that are better than her receptive language skills. This pattern of language development can often be seen in children with autism or autism spectrum disorder. Nonetheless, [she] does not have any other supporting features of autism/autism disorder." *Id*. at 4. "Based on this evaluation, [A.C.] manifests mental developmental delay with current cognitive function within the borderline normal range." *Id*.

II. Procedural History

Petitioner first contacted Attorney Howard Gold on June 20, 2016. *Id*. at 5. Thereafter, counsel reviewed initial medical records and drafted the petition. *Id*. The petition was filed on July 20, 2016. Pet. On August 6, 2016, Mr. Gold traveled to Maryland for an in-person meeting with Petitioner. Fees App. at 5. The following month, Mr. Gold reviewed medical records (*id*.), and filed records on October 6, 2016, March 20, 2017, and May 12, 2017. ECF Nos. 9, 20-21. Petitioner filed her affidavit on March 20, 2017. ECF No. 19.

Respondent filed a Rule 4(c) Report ("Resp't's Report", ECF No. 26) on May 23, 2017, stating that Petitioner did not meet "her *prima facie* burden to show causation-in-fact" and that "this case should be dismissed." Resp't's Report at 11. Specifically, Respondent argued that Petitioner did not present a "plausible medical theory by which DTaP and Hib vaccinations (received when A.C. was two months old) can cause" A.C.'s alleged injuries, or that the

[6] The medical records mention A.C.'s Infants and Toddlers evaluation that found her eligible for early intervention services. Ex. 5 at 2. Regarding such services, it is noted that she "received both physical therapy and special instruction for a number of months. Once she achieved her gross motor goals and was walking independently, services were discontinued." *Id*.

vaccinations "did so in this case." *Id*. at 9. Respondent also noted that Petitioner did not provide an expert report in support of her claim. *Id*. Respondent asserted that Petitioner did not establish onset of A.C.'s symptoms in order to establish a medically appropriate timeframe between vaccinations and onset. *Id*. at 10. Respondent further questioned reasonable basis for Petitioner's claim because his review of the record reflects "more than [a] 10-month delay between [A.C.'s] vaccinations and Dr. Dhruva's first noted concern regarding developmental delay on June 2, 2014[.]" *Id*. at 11, n.8.

Mr. Gold reviewed Respondent's report on May 23, 2017. Fees Application at 6. Petitioner requested extensions of time to file an expert report on August 15, 2017 and October 13, 2017, and contacted an expert on October 30, 2017. *Id*. at 7. Mr. Gold provided the prospective expert with records on November 24, 2017 (*id*.) and requested additional time on December 4, 2017 to file an expert report as "[c]ounsel has encountered difficulty in consulting with Petitioner to determine next steps" (ECF No. 36). Mr. Gold spoke with Petitioner on January 3, 2018 and March 27, 2018; on March 27, 2018, counsel informed the Court that "Petitioner has been unable to obtain an expert report in support of her petition" and that "Counsel has informed Petitioner that he intends to withdraw[.]" ECF No. 38 at 1.

I held a status conference on May 17, 2018, in which Mr. Gold informed me that Petitioner was in the process of seeking new counsel in this case as well as determining how she wished to proceed. ECF No. 43.

On May 24, 2018, Petitioner filed a Motion for Interim Attorneys' Fees and Costs. ECF No. 44. Respondent filed a response to such motion on May 30, 2018 ("Resp't's Resp.", ECF No. 45), and Petitioner filed a reply on June 5, 2018 ("Pet'r's Reply", ECF No. 47). On June 20, 2018, Petitioner filed a status report, expressing that she "has decided not to pursue this case further with other Counsel" and that she "will file a Motion to Dismiss with this Court." ECF No. 48.

Petitioner filed a Motion for a Decision Dismissing Petition (ECF No. 49); a decision dismissing the petition for insufficient proof was issued on June 29, 2018. ECF No. 50. Judgment was entered on July 30, 2018. ECF No. 53.

The matter of *final* attorneys' fees and costs in this case is now ripe for a decision.[7]

III. Parties' Arguments

While Respondent has no objection that the petition was filed in good faith, Respondent argues that "Petitioner's claim lacked a reasonable basis when filed, and one was never established." Resp't's Resp. at 4. Respondent, reiterating his question of reasonable basis as reflected in his Rule 4(c) Report, notes that "the first time a physician noted any concerns with A.C.'s development was not until more than ten months later, on June 2, 2014[.]" *Id*. at 1-2. Respondent states that "a special master may not award compensation 'based on the claims of a

[7] Petitioner filed a status report on June 29, 2018, requesting that "her Motion for Interim Attorney's Fees and Costs be treated as the Final Motion for Attorney's Fees and Costs." ECF No. 51.

petitioner alone, unsubstantiated by medical records or by medical opinion.'" *Id*. at 2 (citing 42 U.S.C. § 300aa-13(a)(1)). Respondent further states that in order for a claim to have a reasonable basis, such claim must, "at a minimum, be supported by medical records or medical opinion." *Id*. at 2-3 (citing *Everett v. Sec'y of Health & Human Servs.*, No. 91-1115V, 1992 WL 35863, at *2 (Cl. Ct. Spec. Mstr. Feb. 7, 1992)). In sum, Respondent believes that the record lacks objective evidence, and therefore Petitioner has no reasonable basis to support that A.C.'s "July 22, 2013 vaccinations caused A.C.'s developmental delays." *Id*. at 4.

Petitioner replied to Respondent's Response on June 5, 2018. Pet'r's Reply. Petitioner cites to the following records in support of a reasonable basis: (1) Petitioner's affidavit reflecting onset of A.C.'s symptoms; (2) notations by A.C.'s treating physicians; and (3) Pentacel vaccine package insert. *See generally id.* Addressing Respondent's argument that onset occurred in June 2014, Petitioner notes that this case involves an infant who "cannot self-advocate" and that "discerning developmental milestones in newborns is difficult." *Id*. at 4. Further, "children cannot advocate for themselves at the age of 2 months and rarely show signs of developmental delays because of the wide-spectrum of acceptable milestones during infancy." *Id*. at 6. Lastly, Petitioner states that she "does not rely on the fact that the case was brought to Counsel immediately prior to the expiration of the statute of limitations to justify the existence of reasonable basis." *Id*. at 5.

IV. Applicable Law

Under the Vaccine Act, an award of reasonable attorneys' fees and costs is mandatory where a Petitioner is awarded compensation; where compensation is denied, as it was in this case, the special master must first determine whether the petition was brought in good faith and whether the claim had a reasonable basis. § 15(e)(1).

The good faith requirement is met through a subjective inquiry. *Di Roma v. Sec'y of Health & Human Servs.*, 1993 WL 496981, at *1 (Fed. Cl. Spec. Mstr. Nov. 18, 1993). Such requirement is a "subjective standard that focuses upon whether [a] petitioner honestly believed he [or she] had a legitimate claim for compensation." *Turner v. Sec'y of Health & Human Servs.*, 2007 WL 4410030, at *5 (Fed. Cl. Spec. Mstr. Nov. 30, 2007). Without evidence of bad faith, "petitioners are entitled to a presumption of good faith." *Grice v. Sec'y of Health & Human Servs.*, 36 Fed. Cl. 114, 121 (1996). Thus, so long as Petitioners had an honest belief that their claim could succeed, the good faith requirement is satisfied. *See Riley v. Sec'y of Health & Human Servs.*, 2011 WL 2036976, at *2 (Fed. Cl. Spec. Mstr. Apr. 29, 2011) (citing *Di Roma*, 1993 WL 496981, at *1); *Turner*, 2007 WL 4410030, at *5.

Regarding the reasonable basis requirement, it is incumbent on Petitioners to "affirmatively demonstrate a reasonable basis," which is an objective inquiry. *McKellar v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 297, 305 (2011); *Di Roma*, 1993 WL 496981, at *1. When determining if a reasonable basis exists, many special masters and U.S. Court of Federal Claims judges employ a totality of the circumstances test.[8] The factors to be considered under this test

[8] Judges on the U.S. Court of Federal Claims have affirmed instances when the special master employed this test or have remanded a decision when the special master did not. *Chuisano v. Sec'y of Health &*

may include "the factual basis of the claim, the medical and scientific support for the claim, the novelty of the vaccine, and the novelty of the theory of causation." *Amankwaa v. Sec'y of Health & Human Servs.*, No. 17-36V, 2018 WL 3032395, at *7 (Fed. Cl. June 4, 2018). This "totality of the circumstances" approach allows the special master to look at each application for attorneys' fees and costs on a case-by-case basis. *Hamrick v. Sec'y of Health & Human Servs.*, 2007 WL 4793152, at *4 (Fed. Cl. Spec. Mstr. Nov. 19, 2007).

The Federal Circuit has emphasized that reasonable basis "is an objective inquiry" and concluded that "counsel may not use [an] impending statute of limitations deadline to establish a reasonable basis for [appellant's] claim." *See Simmons v. Sec'y of Health & Human Servs.*, 875 F.3d 632, 636 (Fed. Cir. 2017). In interpreting *Simmons*, some judges have determined that an impending statute of limitations should not even be one of several factors the special master considers in her reasonable basis analysis. "[T]he Federal Circuit forbade, altogether, the consideration of statutory limitations deadlines—and all conduct of counsel—in determining whether there was a reasonable basis for a claim." *Amankwaa*, 2018 WL 3032395, at *7.

Unlike the good faith inquiry, reasonable basis requires more than just Petitioners' belief in their claim. *See Turner*, 2007 WL 4410030, at *6. Instead, the claim must at least be supported by objective evidence -- medical records or medical opinion. *Sharp-Roundtree v. Sec'y of Health & Human Servs.*, 2015 WL 12600336, at *3 (Fed. Cl. Spec. Mstr. Nov. 3, 2015). The evidence presented must be "sufficient to give the petitioner a reasonable expectation of establishing causation." *Bekiaris v. Sec'y of Health & Human Servs.*, 2018 WL 4908000, at *6 (Fed. Cl. Spec. Mstr. Sep. 25, 2018). Temporal proximity between vaccination and onset of symptoms is a necessary component in establishing causation in non-Table cases, but without more, temporal proximity "fails to establish a reasonable basis for a vaccine claim." *Id; see also Chuisano*, 116 Fed. Cl. at 287.

Although "special masters have historically been quite generous in finding reasonable basis for petitions," *Turpin v. Sec'y of Health & Human Servs.*, 2005 WL 1026714, at *2 (Fed. Cl. Spec. Mstr. Feb. 10, 2005); *see Turner*, 2007 WL 4410030, at *6-7, the court expects counsel for Petitioner to make a pre-filing inquiry into the claim to ensure that it has a reasonable basis. *See Turner*, 2007 WL 4410030, at *6-7.

V. Analysis

A. Good Faith

Petitioner is entitled to a presumption of good faith, and Respondent does not contest that the petition was filed in good faith. *Grice*, 36 Fed. Cl. at 121. There is no evidence that this petition was brought in bad faith. Thus, I find that the good faith requirement is satisfied.

Human Servs., 116 Fed. Cl. 276, 288 (2014); *Graham v. Sec'y of Health & Human Servs*., 124 Fed. Cl. 574, 579 (2015); *Rehn v. Sec'y of Health & Human Servs*., 126 Fed. Cl. 86, 91-92 (2016); *Allicock v. Sec'y of Health & Human Servs*., 128 Fed. Cl. 724, 726 (2016); *Cottingham v. Sec'y of Health & Human Servs*., 134 Fed. Cl. 567, 574 (2017).

B. Reasonable Basis for the Claims in the Petition

The reasonable basis standard is objective and requires Petitioner to submit some evidence in support of "the claim for which the petition was brought." § 15(e). The petition in this case alleges that A.C. received her DTaP and Hib vaccinations on July 22, 2013, and "thereafter suffered a reaction which was diagnosed as Mental Developmental Delay, Mixed receptive-expressive language disorder and Gross Motor Delay." Pet. at 1. Petitioner states that A.C.'s injury was caused in fact by the DTaP and Hib vaccinations. *Id*. at 2.

Petitioner highlights the following evidence in support of a reasonable basis for filing the petition: (1) Petitioner's affidavit describing onset of A.C.'s screaming and crying episodes; (2) the Pentacel package insert listing adverse reactions to the DTaP vaccine; and (3) notations in the medical records made by A.C.'s treating physicians. *See generally* Pet'r's Reply. After my careful study of the record and as discussed in more detail below, I do not find the claims articulated in the petition to be supported by objective evidence.

1. Petitioner has not Presented Evidence of Causation

Petitioner has not presented evidence (medical records or medical opinion) that the DTaP and Hib vaccines A.C. received on July 22, 2013 caused her mental developmental delay, mixed receptive-expressive language disorder, and/or gross motor delay 10 months later. None of A.C.'s treating physicians linked the DTaP and Hib vaccinations to her condition. Further, Petitioner did not file an expert report articulating a link between A.C.'s vaccinations and the onset of her developmental delays. While Petitioner argues she has established some evidence that A.C. experienced screaming and/or crying episodes after her two-month vaccinations, there is no evidence in this record that links screaming and/or crying (a non-specific symptom) to developmental delay whose onset is 10 months later. Thus, there is no reasonable basis for the claim of causation-in-fact set out in the petition.

2. Evidence and Arguments Presented by Petitioner do not Support a Finding of Reasonable Basis

Petitioner avers that her affidavit, the Pentacel package insert, and the medical records support "a vaccine injury" and thus establish reasonable basis to file the petition. I do not agree, as there is no evidence which links inconsolable crying to developmental delay 10 months later.

a. *Affidavit*

In her affidavit, Petitioner states that A.C. received her DTaP and Hib vaccinations on July 22, 2013, and that "[d]uring the evening hours on the day of her vaccinations, [A.C.] began having episodes [of] high-pitched screaming." Ex. 2 at 1. Petitioner described A.C.'s screaming and crying as "episodic" and that "these events increased after each of these shots." *Id*. at 2. The statements of Petitioner alone are statements that, at best, show a temporal sequence of events.

b. *Pentacel Package Insert*

Petitioner filed a vaccine package insert on June 5, 2018.[9] The manufacturer's package insert for the Pentacel vaccine provides prescribing information as well as a description of adverse reactions to the vaccine. Sanofi Pasteur Inc., Pentacel (2008), filed as Ex. 9. "Pentacel is a vaccine indicated for active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease due to Haemophilus influenzae type b." Ex. 9 at l. The package insert states that "[r]ates of adverse reactions varied by dose number. Systemic reactions that occurred in >50% of participants following any dose included fussiness/irritability and inconsolable crying." *Id*. Such data was gathered from clinical studies, and the adverse reaction information gathered "provide[s] a basis for identifying the adverse events that appear to be related to vaccine use and for approximating rates of those events." *Id*. at 8. If "persistent, inconsolable crying lasting ≥ 3 hours within 48 hours … of administration of a pertussis vaccine, [occurs] the decision to administer Pentacel should be based on careful consideration of potential benefits and possible risks." *Id.* at 7. While the Pentacel package insert mentions inconsolable crying, nothing in this document links inconsolable crying to developmental delay or indicates that developmental delay can result from the Pentacel vaccine.[10]

c. *Medical Records*

Petitioner cites to notations in the medical records indicating that A.C. had an allergy and a bad reaction to the DTaP vaccination as objective evidence supporting her reasonable basis to file the petition. *See* Ex. 4 at 38 (under discussion notes, the record states: "has had bad reaction with DTP in past."); *Id.* at 35 (allergies listed on February 26, 2015 as "PENTACEL DTAP-IPV COMPNT"). Petitioner argues that references to an allergy allude to A.C.'s crying episodes. *See* Pet'r's Reply. However, on June 15, 2016 at her three-year well child exam, the records state: "PENTACEL DTAP-IPV COMPNT (PF): Hives (moderate) – diarrhea also". Ex. 4 at 1. This entry suggests that references to an allergic reaction to the DTaP vaccine concerned A.C.'s

[9] The date of filing makes it unclear whether Petitioner considered this package insert in support of filing the petition. Because Petitioner has supplied this information in support of her claim, I will consider it in my analysis.

[10] Further, I note that special masters generally consider package inserts as unpersuasive evidence of causation. *See, e.g., Sullivan v. Sec'y of Health & Human Servs.*, No. 10-398V, 2015 WL 1404957, at *20 (Fed. Cl. Spec. Mstr. Feb. 13, 2015) ("Statements contained in vaccine package inserts do not constitute reliable proof of causation, and cannot be deemed admissions that the vaccines in question have the capacity to harm a particular petitioner in a specific manner."); *Werderitsh v. Sec'y of Health & Human Servs.*, No. 99–319V, 2005 WL 3320041, at *8 (Fed. Cl. Spec. Mstr. Nov. 10, 2005) (quoting 21 C.F.R. § 600.80(l) as saying "[a] report or information submitted by a licensed manufacturer ... does not necessarily reflect a conclusion by the licensed manufacturer or FDA that the report or information constitutes an admission that the biological product caused or contributed to an adverse effect"); *Coppola v. Sec'y of Health & Human Servs.* No. 09-631V, 2012 WL 1118849, at *26 (Fed. Cl. Spec. Mstr. Mar. 7, 2012) (special master rejecting a petitioner's reliance on vaccine package insert information to be indicative of alleged vaccine causation).

development of hives and diarrhea, and not inconsolable crying.[11]

Petitioner also cites to A.C.'s four-month well child exam, where the HPI section of the record states: "[v]ery fussy recently, high-pitched screaming and crying." Ex. 6 at 2. Contrary to Petitioner's assertion that this entry establishes reasonable basis, the notation suggests that the high-pitched screaming and crying started "recently". There is no mention in the records that the high-pitched screaming and crying had been ongoing since A.C.'s two-month vaccinations, much less that high-pitched crying led to developmental delay 10 months later.

Petitioner also notes several entries in the medical records which state that A.C. experienced crying/screaming after receiving her two-month vaccinations. The assessment performed by Harford County Infant and Toddlers Program when A.C. was 13 months old notes that "Mrs. Carter expressed concerns with frequent screaming fits that [A.C.] has done since she was two months old. … Mrs. Carter reports the first time was the day after [A.C.]'s two month immunizations." Ex. 7 at 2. Although not mentioned by Petitioner, during A.C.'s three-year well child visit, the record under HPI states, "Of note, patient had prolonged crying after vaccines at age 2 months." Ex. 4 at 3. Additionally, when A.C. was assessed at the Kennedy Krieger Institute in July of 2016, those records indicate that "[p]ast medical history is notable for parental concerns about extreme crying after receiving DPT immunizations, and interruption in the normal/typical immunization schedule." Ex. 5 at 4. In each of these documents, the crying/screaming noted in the records is based on Petitioner's recounting of events that took place between 11 and 35 months in the past. These parental reports were not contemporaneous accounts of A.C.'s condition close-in-time to her two-month vaccinations.[12]

While these reports in the medical records are not contemporaneous, they may constitute some evidence that A.C. had episodes of extreme crying and/or screaming after her two-month vaccinations. However episodes of crying and screaming are not the same thing as developmental delay. Petitioner needed to submit either medical records or an expert report in order to establish such a connection. *See* § 13 (a)(1). Neither was submitted in this case.

3. Petitioner has not Presented Evidence of an Appropriate Temporal Interval

The first notation in the medical records regarding developmental delay was on June 2,

[11] Of note, "PENTACEL DTAP-IPV COMPNT" was not listed as an allergy until A.C.'s 18-month well visit. (Ex. 4 at 35). *See* Ex. 6 at 1 (at A.C.'s four-month well appointment under "Allergies" the record states, "NKDA" or no known drug allergies); see Ex. 4 at 21 (the "Allergies" section of A.C.'s six-month well exam also indicates that A.C. had no known drug allergies); see Ex. 4 at 25 (A.C.'s 12-month well visit established that Dr. Dhruva "reviewed allergies" and that A.C. has no known drug allergies).

[12] A review of A.C.'s medical records shows no such concerns raised by Petitioner in the months following A.C.'s two month vaccinations (*See* Ex. 6 at 1-4; Ex. 4 at 21-24); in fact, the records demonstrate that A.C. continued to receive her vaccinations on schedule until she was 12 months old.

2014, when A.C. was 12.5 months old.[13] There is a lack of evidence in the record that screaming/crying after two-month vaccinations can or did result in developmental delay more than 10 months later. Petitioner offered no literature or scientific support to show why A.C.'s developmental delay did not manifest until more than 10 months after her vaccinations.[14] Indeed, 10 months after vaccination is too long an interval to be medically appropriate to infer causation.

Petitioner's argument regarding the difficulties in discerning developmental milestones in newborns is not persuasive. *See* Pet'r's Reply at 4; *see id*. at 5 ("fact that the pediatrician did not comment on developmental delays until June 2014 does not mean that it did not occur earlier"); *see also id*. at 6 (children of two months of age "rarely show signs of developmental delays because of the wide-spectrum of acceptable milestones during infancy"). There are established and accepted developmental milestones for children; this includes milestones for children 12 months of age and younger.[15] A.C.'s well visits documented her development with specificity. Each visit included assessments in all four categories established by the CDC. *See* Ex. 6 at 3; Ex. 4 at 23, 27. There was no evidence of developmental delay at her four-month or six-month appointments. Further, Petitioner did not bring A.C. in to the doctor at any point in advance of the 12-month well visit for an evaluation due to developmental concerns. It is not reasonable to assume A.C. experienced developmental delays that her treating physicians failed to recognize.

In summary, none of A.C.'s treating physicians linked A.C.'s vaccinations at two months to her developmental delay at 12 months. Petitioner did not file an expert report in support of the petition. Because Petitioner did not submit objective evidence to support her claim, I conclude that she did not have a reasonable basis to file the petition.

VI. Conclusion

Based on the foregoing, I hereby **DENY** Petitioner's Motion for Attorneys' Fees and Costs. The clerk shall enter judgment accordingly.[16]

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[13] A.C.'s development was examined by her doctor prior to June 2014 and was unremarkable. *See* Ex. 4 at 16; Ex. 6 at 3; Ex. 4 at 23.

[14] *See Anderson v. Sec'y of Health & Human Servs.*, 131 Fed. Cl. 735 (2017), *aff'd* 717 Fed.Appx. 1009 (Fed. Cir. 2018) (Then-Chief Judge Braden affirmed the special master's finding that there existed no temporal relationship between the child's MMR vaccination and subsequent development of autism spectrum disorder, as there was no evidence that the child suffered from a regression or developmental problem until six months after receipt of the MMR vaccination).

[15] The Centers for Disease Control and Prevention (CDC) lists expected milestones by age. These milestones are divided into four categories: social and emotional, language/communication, cognitive, and movement/physical development. *See* https://www.cdc.gov/ncbddd/actearly/milestones/index.html (last accessed on October 9, 2018).

[16] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party filing a notice renouncing the right to seek review.

IT IS SO ORDERED.

s/ Katherine E. Oler
Katherine E. Oler
Special Master